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Clinical Evaluations of Plaque Removal Efficacy:

An Advanced Rotating-Oscillating Power Toothbrush versus a Sonic Toothbrush

Aaron R. Biesbrock, DMD, PhD, MS[1]

Robert D. Bartizek, MS[1]

Patricia A. Walters, RDH, MSDH, MSOB[1]

Paul R Warren, LDS[1]

MaryAnn Cugini, RDH, MHP[2]

CR Goyal, DDS[3]

J. Qaqish[3]

Correspondence to: Dr. Aaron Biesbrock, The Procter & Gamble Company, 8700 Mason-Montgomery-Road, Mason, OH 45040-9462 E-mail: biesbrock.ar@pg.com.

[1]Procter & Gamble Company, Mason, OH, USA.

[2]The Forsyth Institute, Boston, MA, USA.

[3]BioSci Research Canada Ltd, Mississauga, Ontario. Canada.

Abstract

Objective: To evaluate the safety and plaque removal efficacy of an advanced rotating-oscillating power toothbrush relative to a sonic toothbrush with either a standard or compact brush head.

Methodology: Two studies used a randomized, examiner-blind, 2-treatment, crossover design. In Study 1, subjects were instructed to use their first randomly assigned toothbrush for 5 to 7 days and then, after abstaining from all oral hygiene for 24 hours, were assessed with the Rustogi *et al* Modified Navy Plaque Index. They then brushed for 2 minutes and post-brushing plaque scores were recorded. Subjects were assigned to the alternate toothbrush and the procedures were repeated. In Study 2, subjects alternated using both brushes for approximately 10 days, then had 4 study visits 3-4 days apart. In Study 1, Oral-B® Triumph™ with a FlossAction™ brush head and Sonicare® Elite® 7300 with a full-size, standard, head were compared in a 2-treatment, 2-period crossover study. Study 2 compared Oral-B Triumph with a FlossAction brush head and Sonicare Elite 7300 with a compact head in a 2-treatment, 4-period crossover study.

Results: 50 subjects completed Study 1; 48 completed Study 2. All brushes were found to be safe and significantly reduced plaque after a single brushing. In Study 1, Oral-B Triumph was statistically significantly ($p<0.001$) more effective in plaque removal than Sonicare Elite 7300 with the full-size brush head: whole mouth = 24% better, marginal = 31% better, approximal =21% better. In Study 2, Oral-B Triumph was statistically significantly ($p<0.001$) more effective than Sonicare Elite 7300 with the compact brush head: whole mouth = 12.2% better, marginal = 14.6% better, approximal =12% better.

Conclusion: Oral-B Triumph with its rotation-oscillation action was significantly more effective in single-use plaque removal than Sonicare Elite 7300 with its side-to-side sonic action when fitted with either a standard or a compact brush head.

Introduction

Effective removal of dental plaque is crucial for the control of numerous conditions, such as dental caries, gingivitis and for the prevention of progressive periodontal disease.[1-4] Regular manual toothbrushing, resulting in the mechanical removal of plaque, can result in satisfactory plaque control. However, to be effective tooth brushing must be carried out using proper technique and for a sufficient duration, typically 2 minutes per brushing. Unfortunately a large proportion of the general population fails to carry out these measures effectively, resulting in a high incidence of plaque-induced gingivitis.[5]

One development aimed at addressing this problem is the introduction of the electric toothbrush. A large number of models are currently available and they differ widely in brush head design, filament pattern and speed and type of motion. If oral hygiene is to be enhanced, it is important to determine which of these toothbrushes offer consistent benefits over manual brushing and which of the many varieties of power toothbrushes are most effective. One of the most popular power toothbrushes was originally developed by Oral-B and used a rotation-oscillation action with a small circular brush head. Short and long-term studies have shown that this brush is significantly more effective than manual brushing.[6,7] A further technical advance was the introduction of a pulsating movement in the direction of the long axis of the filaments; this was combined with the rotation-oscillation action of the brush head in the Oral-B® 3D and 3D Excel models, now known as the Oral-B® ProfessionalCare® Series (Procter & Gamble, Cincinnati, OH, USA).[8,9] Systematic reviews of the relative benefits of a wide range of power toothbrushes and of manual brushing conclude that only brushes with rotation-oscillation action are consistently more effective than manual brushing in reducing plaque and gingivitis in both the short and the long-term.[10,11]

The most recent model to be introduced in the Oral-B ProfessionalCare Series is Oral-B® Triumph™ ProfessionalCare 9000 (Procter & Gamble, Cincinnati, OH, USA) which incorporates

advances in the earlier models within the series, including increased oscillations and pulsations.[12] The development of advanced designed power toothbrushes that deliver superior plaque removal should involve comparative testing to existing marketed toothbrushes. The present studies reported in this paper were therefore undertaken to assess the safety and plaque removal efficacy of Oral-B Triumph with the FlossAction™ brush head, designed with soft, flexible MicroPulse™ bristles to increase approximal penetration and improve plaque removal, versus a sonic power toothbrush with side-to-side action (Sonicare® Elite® 7300, Philips Oral Healthcare, Inc., Snoqualmie, WA, USA) using either a full-size (standard) or a compact brush head.

Materials and Methods

Subjects

Fifty subjects in general good health were recruited in Study 1 and 49 in Study 2. (Subject populations were distinct.) All subjects were power toothbrush users who reported brushing their teeth at least once a day. For inclusion in the studies, subjects needed to have 18 natural teeth (16 for Study 2) with facial and lingual surfaces which were gradable using the refinement of the Rustogi *et al* Modified Navy Plaque Index (RMNPI) [13] and also a whole mouth pre-brushing plaque score of ≥ 0.6 as assessed at the first post-baseline visit. Subjects were excluded from either study on the grounds of neglected dental health or if they had orthodontic appliances or removable partial dentures. Also excluded were subjects receiving active treatment for periodontitis or with any disease or condition that could be expected to interfere with examination procedures or the subject safely concluding the study. Continuance criteria included removal from the study if subjects had any elective dentistry or if they used any oral care products other than the assigned study products during the study. Written informed consent was obtained from each subject before study entry, and the protocol was approved by an institutional review board before study initiation.

Study devices

The toothbrushes used in these studies were:

- Oral-B Triumph (Figure 1). This power brush has a round brush head and a three-dimensional motion (rotation-oscillation plus pulsation). It operates at 8,800 oscillations / 40,000 pulsations per minute. The toothbrush was fitted with a FlossAction brush head.

- Sonicare Elite 7300 (Figure 1). This power brush has a conventionally shaped brush head and a side-to-side motion. It operates at a frequency of 260 Hz. The Easy-Start feature was deactivated prior to use and the brush was used on the normal setting. This toothbrush can be used with either the standard, full size brush head (Study 1) or a newly designed compact brush head intended for smaller mouths and precision cleaning (Study 2).

<< Insert Figure 1 about here>>

Oral-B Triumph was used in both studies; in Study 1, Oral-B Triumph was compared with the Sonicare Elite using the standard brush head; in Study 2, the comparison was with the Sonicare Elite compact brush head.

Colgate Cavity Protection (Colgate Palmolive, New York, NY, USA) toothpaste was used in Study 1 and Crest Cavity Protection (Procter & Gamble, Cincinnati, OH, USA) in Study 2.

Study Design

The two studies both used an examiner-blind, randomized crossover design to examine the efficacy and safety of the two power toothbrushes in the removal of plaque after a period of home use. Study 1 used a 2-treatment, 2-period (AB/BA) crossover design; for Study 2 a 2-treatment, 4-period

design was adopted with the following treatment sequences: AABB/ABBA/BBAA/BAAB. This 4-period, 4-sequence design was selected for Study 2 because it is the optimal 4-period design for estimating treatment effects and carryover effects.[14] Whole mouth plaque was measured by RMNPI on all tooth areas (A-I) on both buccal and lingual surfaces of the entire dentition, using a score of 0 = absent or 1 = present. Surfaces were disclosed using Chrom-O-Red® erythrosin FD&C red 3 solution (Germiphene Corp., Bradford, Ontario) to stain for presence of plaque. Subjects swished with 20 drops of solution for 15 seconds, expectorated, rinsed with 10 ml of tap water for 10 seconds and expectorated. The total number of tooth areas with plaque present was divided by the total number of tooth areas scored to calculate the mean RMNPI score for each subject (Figure 2). Subjects' RMNPI scores were calculated on a whole mouth basis (areas A-I), along the gingival margin (areas A, B, C) and interproximally (areas D and F). Plaque examinations were performed by a trained, experienced dentist who has previously demonstrated the ability to differentiate treatment effects.[15]

<<Insert Figure 2 about here>>

Eligible subjects, as determined at the first post-baseline visit, were randomized to two treatment sequences in Study 1 and four sequences in Study 2 as detailed above.

At the baseline visit, an oral hard and soft tissue examination together with a medical history review was conducted and recorded. In Study 1, subjects were given their first randomly assigned toothbrush and standard dentifrice, and provided with written manufacturer's usage instructions. They were asked to use these products twice each day and to put aside all other oral hygiene products for the duration of the study. Subjects used brushes for approximately one week prior to exams. They were reminded to abstain from all oral hygiene for 24 hours prior to that visit, to refrain from eating and smoking in the previous four hours and to bring their toothbrush with them.

At the next visit subjects received assessments of all soft and hard oral tissues. The RMNPI was then assessed and all subjects with a mean pre-brushing plaque score of ≥0.6 were enrolled in the study. Qualified subjects brushed for two minutes with the brush they had used since the first visit, in the absence of mirrors and out of the view of the clinical investigator. Enough toothpaste was provided to cover the brush head. After brushing, teeth were again disclosed and plaque was evaluated. Subjects were given the next toothbrush and instructed again to brush twice daily, not use any other oral hygiene products and to return in approximately 7 days for the next visit. They were also reminded to abstain from all oral hygiene for 24 hours prior to that visit, to refrain from eating and smoking in the previous four hours and to bring their toothbrush with them. The procedure was the same at the next visit, after which Study 1 terminated.

In Study 2, subjects were given both study toothbrushes (with written usage instructions) and standard dentifrice at the baseline visit. They were asked to alternate the use of the two toothbrushes for 2-day periods over approximately 10 days prior to their first plaque examination. The same oral hygiene abstention and examination procedures were used as in Study 1. Study 2 continued for a further 3 visits (4 post-baseline visits in all) with washout periods of 3-4 days between visits. Subjects used their normal at-home toothbrush and dentifrice during these washout periods. At the final visit in both studies, an oral safety assessment was conducted and any treatment related adverse events were recorded. The same clinician, who was blind to treatment assignment, examined all subjects throughout each study.

Data analysis

The primary analysis variable was the pre-brushing minus post-brushing reduction in whole mouth RMNPI score. The reductions in scores for the marginal and approximal areas were secondary analysis variables. Analysis of variance (ANOVA) was used to compare treatment groups for baseline

RMNPI scores and reductions in RMNPI scores. For each variable, an initial analysis was performed to test for the presence of differential carryover effects between the treatment groups. In Study 2, if evidence of differential carryover effects were found then the treatment comparison was performed using an ANOVA model with terms for subjects, treatment groups, study periods and carryover effects. If no carryover effects were detected then the treatment comparison was performed using a model without the carryover effects term. Within-treatment analyses of RMNPI reductions were performed using t-tests. All statistical tests were two-sided and used a significance level of α=0.05.

Results

Fifty subjects were enrolled in Study 1, all of whom completed the study. Forty-nine subjects were enrolled in Study 2, of whom one voluntarily withdrew at Visit 3 due to scheduling problems. No subject withdrew from either study because of adverse effects related to treatment. Table I displays the demographic information for both studies.

<<Insert Table I about here>>

In both studies the treatment groups were well balanced and there were no significant differences in pre-brushing RMNPI scores. In both studies, both brushes showed statistically significant reductions in RMNPI scores from pre-brushing to post-brushing (all $p<0.001$).

For each study, a preliminary analysis of RMNPI reductions was performed to test for differential carryover effects between the 2 treatment groups. In Study 1, no statistically significant differential carryover effect was detected ($p \geq 0.322$). In Study 2, no statistically significant differential carryover effects were detected for whole mouth ($p=0.315$) or approximal ($p=0.497$) reductions in RMNPI scores. For marginal reductions, this test yielded $p=0.082$, thus the comparison of treatments was

performed using an ANOVA with carryover in the model. Because the 4-period design was used, the treatment comparison was valid even though carryover effects were present.

Comparison of the changes from pre to post-brushing RMPI scores between treatment groups are presented in Table II and Figures 3 & 4. These results show that statistically significantly ($p<0.001$) more plaque was removed with Oral-B Triumph than with Sonicare Elite using the standard head (Study 1).

<<Insert Table II and Figures 3 & 4 about here>>

This was true for the whole mouth scores (24% better) and also for the marginal (31% better) and approximal (21% better) areas. Similarly in Study 2, where the compact head was used with the Sonicare Elite handle, the advantage to Oral-B Triumph was statistically significant ($p<0.001$) for the whole mouth (12.2% better), marginal (14.6% better) and approximal (12% better) scores.

In neither study was there any report of any treatment related adverse effects and all oral safety examination findings were normal.

Discussion

A wide range of power toothbrushes are now available; they vary in brush head design, mode of action, and filament pattern. Results from the present studies show that both Sonicare Elite, with either a standard or compact head, and Oral-B Triumph were safe and effective in removing plaque from whole mouth, marginal and approximal surfaces. In both studies, Oral-B Triumph was statistically significantly more effective than Sonicare Elite with respect to all three measurements. In particular, plaque removal in the hard-to-reach approximal regions was 21% better than for Sonicare Elite with

the standard head and 12% better than for Sonicare Elite with the compact head. The superiority of Oral-B Triumph over Sonicare Elite with both brush heads reflects an advantage of the rotation-oscillation action over the side-to-side action. Furthermore, these findings confirm the efficacy of the Oral-B FlossAction brush head in plaque removal. Previous comparisons of Oral-B power toothbrushes with rotation-oscillation action and Sonicare toothbrushes with side-to-side motion have found similar advantages for the Oral-B brushes.[16-18] Comprehensive surveys of the literature comparing the efficacy of power and manual toothbrushes have also concluded that only those power brushes with a rotation-oscillation action are reliably superior to manual brushing in removing plaque.[10,11] The relationship between supragingival plaque removal in one-to-three month studies and long-term disease (e.g., caries, periodontal disease) has not been clearly established.

The present studies were conducted according to fundamentally different clinical designs. The earlier study of the two was a two-treatment, two-period crossover design where each on-site plaque evaluation was preceded by one-week's usage of the toothbrush to be tested on-site. There was no formal washout period between uses of the test toothbrushes. A general weakness in designs of this type is that they are vulnerable to the presence of carryover effects which, if present, require drastic changes to the statistical analysis. Fortunately, carryover effects were not found in the analysis of this study. The more recent study was a two-treatment, four-period crossover design. In this study, subjects used both toothbrushes at home prior to their first on-site test. The four on-site evaluations were separated by washout periods where subjects used their usual at-home toothbrush and toothpaste. The design of this more recent study allowed valid treatment comparisons to be performed whether or not carryover effects are evident. In fact, some evidence of carryover effects for plaque reduction along the gingival margin was detected in the study ($p=0.082$).

Although the findings reported here are based on plaque removal in a single-use situation, there is evidence that such short-term effects translate into long-term benefits in oral hygiene and, in

particular, in the control of gingivitis. Rosema *et al*[19] carried out a study in which gingivitis was induced by not brushing for three weeks; this was followed by four weeks of regular brushing with either an Oral-B ProfessionalCare or a Sonicare Elite power toothbrush. Both in terms of plaque removal and, more importantly in the long-term, improvement of the gingival condition, the Oral-B brush was significantly more effective. A similar study by Van der Weijden *et al* also reported better efficacy of Oral-B than Sonicare power toothbrushes in the resolution of gingivitis.[20] It appears therefore that the benefits found in short-term trials such as those reported here can be expected to result in longer-term gains in oral health; however longer-term comparisons with Oral-B Triumph are needed to confirm this conclusion.

Modern toothbrush design has produced major, clinically-proven benefits in the control of plaque and of gingivitis.[12,15, 17, 21, 22] Despite these improvements, the prevalence of periodontal problems in the general population remains high[5] as compliance with the recommendations of dental professionals is limited, particularly with regard to the two minute brushing time.[23-25] If the full benefits of improved toothbrush design are to be realized, it is essential that home-use compliance is improved and it may well be that the greatest future improvements in oral health will derive from devices that increase compliance. Advances in technology can greatly expand the opportunities for improving compliance, by, for example, providing immediate visual feedback during toothbrushing; such feedback is known to be effective in modifying behaviour.[26,27] A number of power toothbrushes, including some in the Oral-B range have incorporated two minute timers, but these have been mounted in the handle where they do not give immediate visual feedback. The new Oral-B Triumph with SmartGuide™ uses wireless technology to provide a remote display which can be placed on the counter, or anywhere within 10-15 feet of the user. This device gives immediate visual feedback for total brushing time and quadrant time; it also has a signal that lights up if too much pressure should be applied.[28] This enhancement offers unique opportunities for increasing compliance.

Conclusion

The Oral-B Triumph rotating-oscillating power toothbrush was significantly more effective in plaque removal after a single use than the Sonicare Elite brush, with either the standard or compact head. This advantage was clear not only on whole mouth surfaces but also on approximal surfaces, which are hard to clean effectively.

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Table I

Demographic Characteristics

	Study 1 (n = 50)	Study 2 (n = 48)
Mean age (range): years	41.1 (18-64)	43.5 (20-67)
Male/female	14/36	14/34

Table II

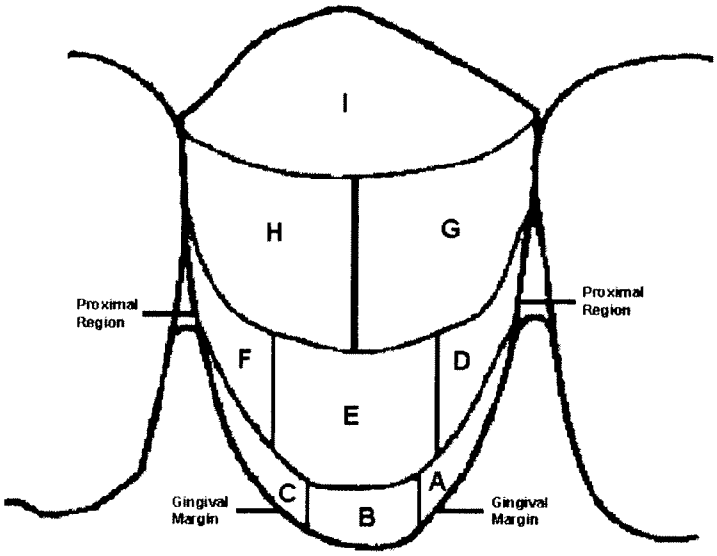
Pre- brushing RMNPI and post-brushing plaque reduction for Studies 1 and 2

		Pre-Brushing (mean ± SD)	Post-brushing Plaque Reduction (Mean ± SD)	% Plaque Reduction
Study 1 (N=50)				
Whole mouth	A = Sonicare Elite	0.6275 ± 0.03	0.4362 ± 0.06	69.51
	B = Oral-B Triumph	0.6244 ± 0.03	0.5420 ± 0.03	86.81
			B 24% greater than A	p<0.001
Marginal	A = Sonicare Elite	1.000 ± 0.00	0.6323 ± 0.12	63.23
	B = Oral-B Triumph	1.000 ± 0.00	0.8275 ± 0.07	82.75
			B 31% greater than A	p<0.001
Approximal	A = Sonicare Elite	1.000 ± 0.00	0.7662 ± 0.11	76.62
	B = Oral-B Triumph	1.000 ± 0.00	0.9252 ± 0.06	92.54
			B 21% greater than A	p<0.001
Study 2 (N = 48)			**(Adjusted Mean ± SE)**	
Whole mouth	A = Sonicare Elite	0.620 ± 0.029	0.448 ± 0.004	72.3
	B = Oral-B Triumph	0.618 ± 0.028	0.503 ± 0.004	81.3
			B 12.2% greater than A	p<0.001
Marginal	A = Sonicare Elite	1.000 ± 0.001	0.662 ± 0.007	66.2
	B = Oral-B Triumph	1.000 ± 0.001	0.758 ± 0.007	75.8
			B 14.6% greater than A	p<0.001
Approximal	A = Sonicare Elite	1.000 ± 0.002	0.794 ± 0.007	79.4
	B = Oral-B Triumph	1.000 ± 0.002	0.890 ± 0.007	89.0
			B 12.0% greater than A	p<0.001

SD standard deviation
SE standard error from crossover ANOVA

A. 	 **B.** Placebholder – better image coming	 **C.** Placebholder – better image coming

Figure 1. *Brush heads: (a) Oral-B Triumph - FlossAction brush head, (b) Sonicare Elite - full-size head, (c) Sonicare Elite - compact head.*



Disclosed plaque is scored in each tooth area as present (scored as 1) or absent (scored as 0) and recorded for both buccal and lingual surfaces. Whole mouth = areas A, B, C, D, E, F, G, H and I; Marginal (gumline) = areas A, B and C; Interproximal (approximal) = D and F.

Figure 2. Rustogi *et al* Modification of the Navy Plaque Index.[13]

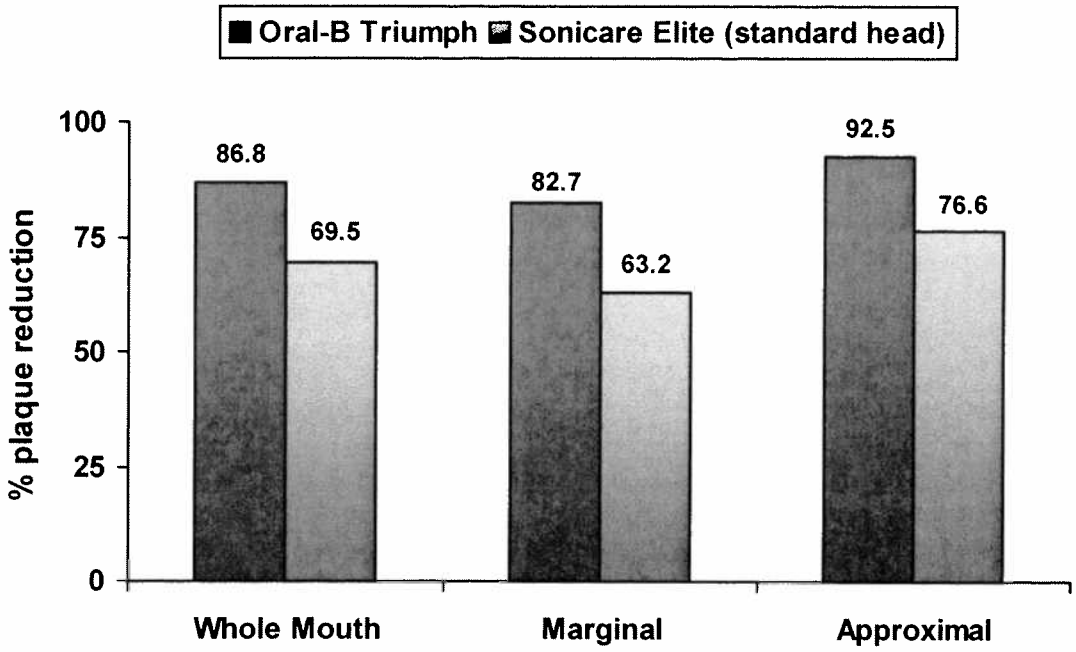


Figure 3. *Study 1: Percent plaque reduction.*

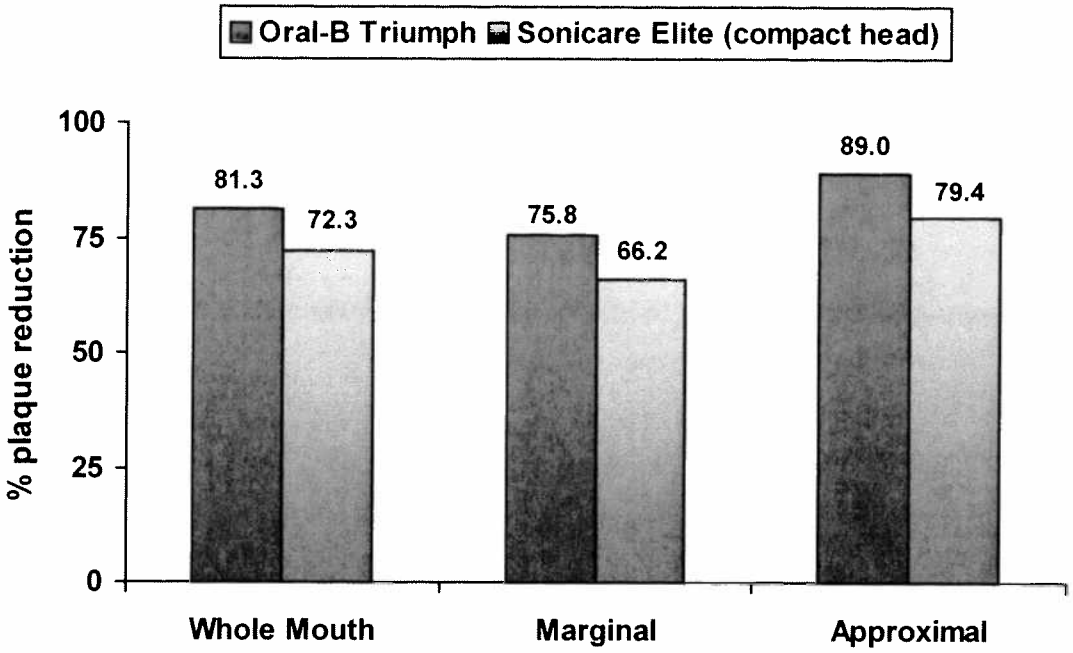


Figure 4. *Study 2: Percent plaque reduction.*